



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

**WASHINGTON STATE BOARD OF PHARMACY
MEETING AGENDA**

July 26, 2007

Marketing Center Creekside Three at CenterPoint
20435 72nd Ave S, Suite 200
Kent, Washington 98032

CONVENE

Chair Rebecca Hille convened the meeting at 9:00 a.m. on July 26, 2007.

Board Members present:

Gary Harris, RPh, Vice Chair
George Roe, RPh
Rebecca Hille, Chair
Rosemarie Duffy, RN
Susan Teil-Boyer, RPh
Vandana Slatter, PharmD
Dan Connolly, RPh

Staff Members present:

Lisa Salmi, Acting Executive Director
Tim Fuller, Pharmacy Consultant
Grace Cheung, Chief Investigator
Richard Morrison, Pharmacist Investigator
Jim Doll, Pharmacist Investigator
Tyler Varnum, Pharmacist Investigator
Joyce Roper, Assistant Attorney General
Doreen Beebe, Program Manager
Cheryl Christensen, Office Assistant 3

Guest(s) Present:

Bonnie King, Director, Health Professions Quality Assurance
Tami Thompson, HPQA Policy Manager
Jennifer Sabel, Epidemiologist, Injury Prevention Program

CONSENT AGENDA:

- 1.2** Pharmacy & Other Firm Application Approval
 - Opened and Closed Pharmacy Firms April 26 – July 1, 2007
- 1.4** Pharmacy Tech Training Program Approval
 - Southern Careers Institute in San Antonio TX – Priscilla Guzman
 - Care Health Solutions LLC
 - Lidgerwood Owl Pharmacy
 - Medical Lake Owl Pharmacy
 - Periyar College of Pharmaceutical Sciences for Girls in Trichy Madras – Rajalakshmi Karthikeyau Yuvaraj
 - Career Centers of Texas in El Paso TX – Maria Gomez
 - High Tech Institute in Las Vegas NV – Kara Kinas
 - Houston Community College System in Houston TX – Erica Gomez
 - Cerritos College in Norwalk CA – Asmeret Gebremichael
 - Costco Pharmacy in Brandon FL – Sandra Fernandez
 - Ogden-Weber Applied Technology College in Utah – Gwen Santisteban
 - Abram Friedman Occupational Center in Los Angeles CA – Octavia Smith
 - The Tamil Nadu DR. MGR Medical University in Chennai Tamil Nadu, India – Deepthi Nitta
- 1.5** Collaborative Drug Therapy Agreement Acceptance
 - St Johns's Medical Center – Peacehealth – Warfarin – Various
 - Children's Hospital – Surgical Antimicrobial – Various
 - The Everett Clinic – Immunization & Travel Medication – Various
- 1.8** Board Minute Approval – May 17, 2007

Items 1.1 – Pharmacist License Application Approval; 1.3 – Pharmacy Technician Application Approval; 1.6 – Automated Drug Dispensing Device Acceptance; and 1.7 – Sample Distribution Requests were deleted from the consent agenda. **ACTION:** Rosemarie Duffy moved that the Board approve 1.2, 1.4, 1.5 and 1.8 of the consent agenda. Gary Harris second. **MOTION CARRIED 6-0.**

REPORTS:

Acting Executive Director

Lisa Salmi reported:

- Quarterly Investigator meeting was held on June 6th in Tumwater. Dan Connolly represented the Board. Bonnie King met with the investigators to discuss the restructure of Health Systems Quality Assurance.
- Work continues on the HSQA Organizational Restructure. Workgroups have been preparing functional org charts for each office. Workgroups will present proposals to Assistant Secretary Laurie Jenkins on July 31st. Ms Jenkins will then brief Secretary Selecky. Implementation is projected for November or December 2007.
- HSQA is developing a new 2007-2009 Strategic Action Plan.
- The preliminary report on the Performance Audit has been received. The Department of Health is working on a response and the audit has not been made public.

- Workloads Standards Study has begun. Investigators, program managers and disciplinary staff are participating in the study. Participants wear pagers and are alerted during the day and must record their activities at the time of the alert. The study is required by Substitute House Bill 2974 and the focus is on disciplinary activities. The goal is to develop a comprehensive and sustainable measure for allocating workload to respond to changes in case priorities. Study will assist the Department in determining the resources necessary to perform specific activities for specific types of cases. The study is in a pilot phase this week. Data will be collected from August 1st through the 31st. Final report is due to the legislature in December.
- The Pharmacists'/Pharmacies' Responsibilities rules become effective July 26th. To assist pharmacies and pharmacists in complying with the rule a guidance document has been developed and distributed. These rules continue to receive media interest.
- Attended the Drug Enforcement Administration (DEA) Annual Conference on June 4-7. The agenda included discussions on methadone mortality, pain policies, pharmacy theft and scheduling updates. DEA hopes to propose rules to schedule carisoprodol in September.
- There are ongoing discussions with Department of Social and Health Services (DSHS) about federal legislation that requires all outpatient Medicaid prescriptions be written on tamper proof prescription pads. Centers for Medicare and Medicaid Services has not provided a definition of "tamper proof". Faxes, phone, and electronic prescriptions are exempt.
- The Methamphetamine Workgroup report for the Legislature had been drafted and it will be circulated to the department for comments.
- The Medical Quality Assurance Commission will be holding stakeholder meetings during the next few months to determine what constitutes a 60-day supply of marijuana for approved conditions.
- 2007-09 Budgets due out July 31st.
- Upcoming Meetings/Conferences:
 - The NABP District VII & VIII October 3-6 in Ashland, Oregon.
 - September 27-28 DOH Board/Commission/Committee Conference, Renton Holiday Inn
 - October 31-November 2 Citizen Advocacy Center Meeting, Edgewater Hotel, Seattle – to be attended by Dan Connolly and Vandana Slatter (tentative)

Staffing Updates:

- Tyler Varnum joined our staff on July 18th as a Pharmacist Investigator and is assigned to the Central Washington region and is based out of Yakima. He received his PharmD degree from WSU and has served in the U.S. Navy.

Board Member Reports

George Roe attended the NABP Annual Meeting held in Portland, Oregon on May 19th-22nd.

Dan Connolly attended the following:

- Investigator Meeting on June 6th in Tumwater. He commented how impressed he was with the quality of the investigators.
- On June 7-10th, he represented the board at the Tri-State Convention.
- The Methamphetamine Workgroup meeting held June 20th
- WRAPP Meeting on June 22nd. Mr. Connolly remarked how impressed he is with the organization and would like to be on the committee. He suggested that WRAPP present to the board at least once per year.

Rosemarie Duffy had the opportunity to go out with Investigator Bill Kristen and considered it a good experience.

Gary Harris attended the NABP Annual Meeting held in Portland, Oregon on May 19th-22nd. He also had the opportunity to attend the Utah School of Alcoholism and Other Drug Dependencies.

Rebecca Hille also attended the NABP Annual Meeting in Portland, Oregon on May 19th-22nd and found many of the presentations quite educational. She also attended the WRAPP Meeting on June 22nd and feels it is a great program.

ACTION: Rosemarie Duffy motioned to adjourn the Board at 9:15 a.m. to conduct the Rules Hearing, WAC 246-889-050. Susan Teil Boyer second. **MOTION CARRIED 6-0.**

RULES HEARING, WAC 246-889-050

Jim Doll, Pharmacist Investigator, presented a brief background and summary of WAC 246-889-050. A revision of the WAC was mandated by the legislature in 2004, Engrossed Substitute Senate Bill 6478 to further restrict the sale of pseudoephedrine by wholesalers and manufacturers.

The Rules Hearing was divided into two portions: Question/Answer Session and the Public Hearing. There were no questions from the board members.

Mr. Doll read into record a public comment posted to the Department of Health's Public Rules Comment web page that questioned the effectiveness of the rule and the workload impact to Board staff. Mr. Doll explained that the number of over-the-counter drug wholesalers in the state have decrease significantly and many that continue to sell pseudoephedrine products have incorporated computer software that identifies and restricts excessive sales.

The Chair opened the hearing to public testimony – none was given.

ACTION: Dan Connolly moved that the Board adopted the revised rule. Gary Harris second. **MOTION CARRIED 6-0.**

Chair Rebecca Hille reconvened the meeting at 9:30 a.m. on July 26, 2007

Assistant Attorney General

Joyce Roper stated that the Department of Health was served with legal pleading filed by Ralph's Thriftway challenging the Pharmacies' Responsibility Rule.

Consultant Pharmacist

Tim Fuller reported:

- Attended a Nursing Care Quality Commission meeting where the Commission discussed the issue of personnel using standing orders to dispense drugs. The Commission approved a request by Snohomish County Community Health Care to automate this process allowing nurses to renew medication orders. The Commission's approval was based on DOH attorneys' definitions of protocol and stand orders.
- Attended the Utah School of Alcoholism and Other Drug Dependencies.
- As a member of the Emergency Response Group begin planning the Reception Staging Storing processes. A full scale exercise is scheduled for October 31, 2007.

Chief Investigator

Lisa Salmi reported:

- Dick Morrison received a letter from University of Washington promoting Mr. Morrison to Clinical Associate Professor effective July 1st.
- We are currently recruiting for the Chief Investigator position. The duties of Chief Investigator have been divided among investigator staff until a replacement is hired.
- Inspection statistics were provided via a handout for May and June 2007.
- Interviews were held on June 12th for two vacant Investigator positions. Grace Cheung has been selected for the King County position and Tyler Varnum was selected for the Central Washington Region. We continue to recruit for an additional investigator for Western Washington.
- Interviews were held on July 11th for the vacant Pharmacist Consultant position and the position has been informally offered and accepted.
- Randy Flett has returned to the Department to work part-time concentrating on inspection backlog.
- Presentations and meetings attended by Investigative staff included:
 - Stan Jeppesen – gave a presentation to the UW School of Pharmacy and the Children's Medical Center Research Institute on federal and state laws regarding the use of controlled substance and research and licensing requirements on July 17th.
 - Dick Morrison participated in the Human Behavior and Communications class at the UW on May 29th.

- Stan Jeppesen gave a presentation to the UW Hospital Pharmacy staff on Pain Addiction in Professional Healthcare Workers.
- In June, Grace Cheung and Dick Morrison participated in the National Association of Boards of Pharmacy Multi-state Pharmacy Jurisprudence Exam Writing Workshop.

Program Manager

Doreen Beebe reported:

- Citizens Advocacy Center registration is open until September 28th
- New Board Member Orientation will be held on Wednesday, August 8th in Tumwater and it will be attended by Vandana Slatter and Dan Connolly.

DISCUSSION

Request by Group Health to Utilize One Pharmacy Inventory for Two Pharmacies

Tim Fuller briefed the Board on the proposal by Group Health Cooperative to utilize one inventory for two pharmacies located in the same facility. The CMS is requiring a separate National Center for Prescription Drug Program ID number (NCPDP) used for third-party billing for mail order prescriptions.

Dick Morrison, Board Investigator shared concerns not related to GHC's operations, which tracks its inventory electronically, but that the Board's approval may establish a standard for other practices that do not have an adequate tracking system.

- Group Health Cooperative purchases drugs at special pricing under the Robinson Pattman Act for its own use, but not for mail order. GHC will pursue a waiver or exception from the CMS.
- Board staff will research whether there are other options should CMS deny GHC an exception/waiver. **ACTION:** George Roe moved that the Board postpone this decision for additional information/research. Vandana Slatter second. **MOTION CARRIED 6-0.**

Request by SEIU District 1199NW for Public Disclosure

The 1199NW Service Employees International Union request for a list of all practitioners credentialed by the Board of Pharmacy was deferred from the May meeting. **ACTION:** Rosemarie Duffy moved that the Board deny the request as SEIU are not recognized as professional association by the Board. SEIU represent the economic interests of the union and do not represent the issues of the pharmacy profession(s) and do not develop criteria or standards. George Roe second. **MOTION CARRIED 6-0.**

Malley's Pharmacy Requests Extension of Technician Training Program

The board members agreed that they all had the chance to review Malley's Pharmacy request to extend the training of a pharmacy technician beyond one year due to mitigating

circumstances. **ACTION:** Dan Connolly moved to approve the request. Vandana Slatter second. **MOTION CARRIED: 6-0**

Seattle Children's Hospital - Requests Intern Registration for Foreign Graduate

The Board reviewed the proposal by Seattle Children's Hospital and Regional Medical Center to allow Ms. Ying-Jung Chen a pharmacist from Taiwan to serve as an Intern at the hospital and participate in pediatric general medicine and infectious disease rotations. The proposal met the criteria established in Board procedure #31. **ACTION:** Dan Connolly moved that the Board accept the request by Children's Hospital. Rosemarie Duffy second. **MOTION CARRIED 6-0.**

Delegation of Signature Authority

Each biennium the Board must update delegation of signature authority for credentialing, disciplinary, and rules.

ACTION: Vandana Slatter moved that the Board approve the delegation of signature authority for disciplinary documents, credentialing applications and rules as follows:

- Signature Authority to Doreen Beebe for the CR-101, CR-102 and that the CR-103 continue to be signed by the Board chair.
- Signature Delegation Authority for Disciplinary Documents to Janelle Teachman, Section 4 Disciplinary Manager.
- Delegate Signature Authority to Judy Haenke, who will become the Acting Executive Director for Section 4, for credentialing matters for approval of routine credentialing applications. Any exceptional applications would have to come before the Board.

Gary Harris second. **MOTION CARRIED: 6-0**

Citizen Advocacy Center's Conference

The CAC Conference is being co-hosted by the Department of Health. The conference is local, making it a great opportunity for the Board Members to attend. Registration was included in the 2007-09 budget. Dan Connolly has confirmed and a tentative confirmation from Vandana Slatter.

PH:ARM Project Update

The PH:ARM (Pharmaceuticals from Households: A Return Mechanism) program is a pilot project that the Board of Pharmacy authorized to take back household consumer pharmaceutical waste.

Stan Jeppesen updated the Board on the status of the PH:ARM Project:

- Three additional collection sites have been added since the last update, bringing the current total to 11.
- Over 1,800 pounds have been collected and incinerated, however we need a more efficient manner to do so. The current rate of collection is higher than the anticipated forecast.
- Currently using two proto-type containers and would like to begin using them at Bartell Drugs with the Board's approval.

- Statewide implementation could result in collection of 700,000 pounds.
- A presentation on the pilot has been done to Laurie Jenkins, HSQA Assistant Secretary.
- Secretary Mary Selecky and Governor Gregoire have written letters of support to the DEA.
- Pilot funding is primarily from grants, Pacific Northwest Pollution Prevention Resource Center and the Russell Foundation.
- DEA waiver necessary to utilize disposal sites outside of Washington State.

ACTION: Susan Teil Boyer moved that the Board draft another letter to the DEA requesting a waiver for the collection of controlled substances. That the program seek additional support from other sources and send a proposal to NABP for consideration by its Board at the district meeting. George Roe second. **MOTION CARRIED 6-0.**

ACTION: Rosemarie Duffy moved that the Board approve participation by Bartell Drugs in the PH:ARM pilot. Susan Teil Boyer second. **MOTION CARRIED 6-0.**

Dispensing Error Prevention Guidelines

Grace Cheung asked the Board for its views/philosophy regarding dispensing error to help develop uniform and appropriate sanctions guidelines. What Board action is appropriate; and how might the Board's decisions influence errors in the future.

Factors for Consideration

- Frequency
- Degree – Severity
- Input Error
- New or Refill Prescription – Generic or Brand
- Patient Counseling – MedGuides
- Quality Action Plan for first dispensing error
- Quality Assurance Program– Board needs to take the lead in developing a model QA program. Joyce Roper suggests that the Board contact the DOH Coordinated Quality Improvement Program for sample programs. The CQIP approves Quality Improvement plans submitted by health care providers by verifying plans met the minimum requirements for complying with related laws and rules.

Further research would be necessary to determine whether the Board has the authority to mandate a QA program in pharmacies other than hospitals. Hospitals currently have a requirement for QA programs in its licensing requirements.

- Patient Outcomes
- System Related Issues

Grace Cheung and Kristi Weeks will work on formatting a grid for the Board to use in developing a sanction guideline for dispensing errors.

The Board expressed an interest in gathering more information to further define a tool to evaluate appropriate sanctions and uniformity in its disciplinary actions. Staff will make appropriate contacts as suggested. Dan Connolly, George Roe and Gary Harris have volunteered to participate on the sub-committee tasked with looking at dispensing errors sanction guidelines.

ACTION: Susan Teil Boyer moved that the Board establish a sub-committee/task force to include development of guidelines for dispensing errors prevention and appropriate discipline sanctions to bring back to a future meeting. Rosemarie Duffy second.

MOTION CARRIED 6-0.

Delegation for Approval of Continuing Education Audits

The Department of Health audits 2 percent of all practitioners renewing their credentials each month for compliance with CE requirements. The Board was asked to consider delegating to staff the authority to determine if practitioners have met the CE requirements.

ACTION: Susan Teil Boyer moved that the Board delegate approval of CE audit requirements to credential manager. Rosemarie Duffy second. **MOTION CARRIED**

6-0.

Update on Organizational Changes

Lisa Salmi announced she has accepted a position as the Executive Manager of the Accommodations and Residential Care Survey Program and will report to Steve Saxe. Mr. Saxe will be the Acting Pharmacy Board Director in the interim until the position is filled. The Pharmacist Consultants and the Chief Pharmacy Investigator will report to Byron Plan. The Pharmacist Field Investigators will continue to report to the Chief Investigator. The Credentialing and Disciplinary Manager will remain in HPQA Section 4 and will report to Judy Haenke. This is an interim step towards the HSQA reorganization. It will also mean more involvement for Doreen Beebe with the Board. Bonnie King stated she doesn't think the Board will see a change.

PRESENTATIONS

Accidental Poisonings – Jennifer Sabel

Jennifer Sabel of the Department of Health Injury Prevention Program gave a presentation on "Poisoning & Drug Overdose Deaths". Dr. Sabel shared national and local data to show an increase in unintentional poisoning deaths and spoke about prevention strategies.

- Next spring, the Department of Health in conjunction with Labor & Industries will be putting on a conference on this issue.
- The Attorney General's office has a new program for high school students called "Don't Meth Around".

Rules Workshop

Tami Thompson, HPQA Policy Manager provided a brief overview of the administrative rules process including what is a rule, what triggers a rule and the guiding principles for rule development.

Carisoprodol

The decision to move forward on with rule development regarding Carisoprodol was postponed at the May meeting to allow stakeholders to review and provide input on comments received during the electronic stakeholder process. All comments have been shared with the Board.

A support scheduling verses opposed scheduling presentation was provided by Board Sponsor Gary Harris and Pharmacist Consultant Tim Fuller. The subject of the interaction was whether the Board should move forward in the rule making processes by proposing rules to schedule Carisoprodol.

MedPoint representatives Cliff Webster, and Kinsey Reagan, Legal Counsel for MedPoint Pharmaceuticals, and Richard Spivy, Senior Vice President of Research and Development for MedPoint Pharmaceuticals were present during this discussion. FDA labeling changes on carisoprodol products were shared with the Board.

ACTION: Susan Teil Boyer moved that the Board proposed an amendment to the rule to schedule carisoprodol and move forward with filing a CR102. George Roe second.

MOTION CARRIED. 4 to 2 (Vandana Slatter and Rosemarie Duffy opposed)

Extended Care Facilities

ACTION: Rosemarie Duffy moved that the Board proposed version 2 of the amended rule language and move forward with filing a CR102. Susan Teil-Boyer second.

MOTION CARRIED 6-0.

Pharmacy Technicians' National Standardized Examination

The Board reviewed and approved survey questions to gather information on the possible disproportionate financial impact the proposed rule may have on small businesses with Board approved pharmacy technician training programs. **ACTION:** Gary Harris moved to approve the survey for mailing. Vandana Slatter second. **MOTION CARRIED: 6-0**

OPEN FORUM

Rosemarie Duffy requested an update on the Correctional Facilities CR-101 filed in June and the Stakeholder meetings. Doreen Beebe stated the CR-101 went through the review process and was approved in early July and we are in the process of scheduling Stakeholder meetings.

Dick Morrison stated that he was really pleased for Lisa Salmi accepting a new position. He feels that no individual is more dedicated than Lisa and she will be genuinely missed.

Tim Fuller gave kudos to Investigators Jim Doll and Bill Kristen for helping answer telephone calls on Mondays and Fridays. He said that since the other Pharmacist Consultant accepted another position, this has helped him manage his current workload.

Doug Beeman, Group Health Cooperative, asked the Board for information regarding the requirement that all Medicare prescription must be on tamper resistant paper. This requirement is effective October 1, 2007. Lisa Salmi stated it is a federal rule and we are working with DSHS to ensure the information is distributed. The Board has not received information defining a tamper proof prescription pad. Legislation has been introduced to limit it to Schedule II and Washington State Pharmacy Association is campaigning to extend the implementation date. Once we receive information as to what constitutes a tamper proof prescription pad, the department will work to get that information out.

Mr. Beeman also requested clarification regarding a new format for licenses issued by the department. Lisa Salmi stated that license numbers will not change, but there will most likely be a change in the look of licenses. The new licensing system is currently scheduled to go fully live in February 2008, but it is her understanding that Pharmacy will come on in October 2007.

Dan Connolly requested an update on the Prescription Monitoring Program. Lisa Salmi stated we still don't have funding and a letter to Secretary Selecky requesting support has been drafted for Rebecca Hille's signature.

Presentation of Agreed Orders

Business Meeting Adjourned

There being no further business, the Board adjourned at 4:49 p.m. The Board of Pharmacy will meet again on September 6-7 in Spokane, Washington.

Respectfully Submitted by:

Cheryl Christensen, Board Staff

Approved on September 6, 2007

*Rebecca Hille, Chair
Board of Pharmacy*